☐ 1: J Pharm Biomed Anal. 1991;9(7):565-71.

Related Articles, Links

Liquid chromatography assay for amlodipine: chemical stability and pharmacokinetics in rabbits.

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Amlodipine is a long acting dihydropyridine calcium antagonist recently introduced for the treatment of angina and hypertension. In order to document its stability in vitro and to develop a pharmacokinetic model in rabbits, a new reversed-phase liquid chromatography (LC) assay with UV detection was developed. The method utilized a C18 column (250 x 4.6 mm i.d.) with a mobile phase composed of a mixture of methanol 0.04 M ammonium acetate-acetonitrile (38:38:24, v/v/v) containing 0.02% triethylamine (final pH 7.1). Under these conditions, the retention times of amlodipine and the internal standard desipramine were 10.6 and 12.9 min, respectively. Using 1 ml of plasma, sensitivity of the assay was 2.5 ng ml-1 at which the RSD was 11%. The standard curve was linear from 2.5 to 100 ng ml-1 (r2 = 0.990), and the mean RSD at this concentration range was 6.8%. The pharmacokinetic model was developed in rabbits which provides results similar to those in dogs, but at less expense. The assay was also applied to a stability study comparing amlodipine and nifedipine in pH 3 and pH 7 ammonium acetate buffers and in methanol. Amlodipine was considerably more stable than nifedipine under all conditions. Finally the assay was applied to a pharmacokinetic study in rabbits (n = 6) after a single 1 mg kg-1 intravenous dose. The mean half-life (t1/2) of amlodipine was 6.5 h, the systemic clearance (CL) was 4.8 l h-1 kg-1 and the apparent volume of distribution at steady state (Vdss) was 30.2 l kg-1.(ABSTRACT TRUNCATED AT 250 WORDS)

PMID: 1840130 [PubMed - indexed for MEDLINE]

☐ 1: Am J Health Syst Pharm. 1998 Jun 1;55(11):1155-7. Related Articles, Links

Stability of enalapril maleate in three extemporaneously prepared oral liquids.

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The stability of enalapril 1 mg/mL (as the maleate) in deionized water, citrate buffer solution, and a sweetened suspending agent at two temperatures was studied. Twenty enalapril 10-mg tablets were crushed to a powder. Deionized water, citrate buffer solution, or sweetened vehicle was added to produce three 200-mL batches of each liquid; the expected final concentration of enalapril in each was 1 mg/mL. Each formulation was stored in 10 60-mL bottles, 5 of which were stored at 4 degrees C and 5 at 25 degrees C. Samples were collected on days 0, 7, 14, 28, 42, 56, 70, and 91 for visual inspection and analysis by high-performance liquid chromatography; pH was measured at each sampling time as well. The mean concentration of enalapril in the three liquids at 4 degrees C was > 94% of the initial concentration throughout the 91-day study period. At 25 degrees C, the mean concentration of enalapril was > 90% for 56 days and > 92% for 91 days in both citrate buffer solution and sweetened vehicle. The pH of the liquid prepared with deionized water and stored at 25 degrees C decreased by 2.0 pH units. Enalapril 1 mg/mL (as the maleate) in three extemporaneously compounded oral liquids was stable for 91 days at 4 and 25 degrees C with the exception of enalapril in deionized water, which was stable for only 56 days at 25 degrees C.

PMID: 9626379 [PubMed - indexed for MEDLINE]